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12 **IN THE UNITED STATES DISTRICT COURT**
13 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**
14 **OAKLAND DIVISION**

15	_____)	
16	STATE OF CALIFORNIA, <i>et al.</i> ,)	Case No.: 4:17-cv-5783-HSG
17	Plaintiffs,)	
18	v.)	DEFENDANTS' OPPOSITION TO
19	ERIC D. HARGAN, Acting Secretary of)	PLAINTIFFS' MOTION FOR A
20	Health and Human Services, <i>et al.</i> ,)	PRELIMINARY INJUNCTION
21	Defendants.)	Date: December 12, 2017
22	_____)	Time: 2:00 p.m.
)	Courtroom: 2, 4 th Floor
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INTRODUCTION

This case is about religious liberty and freedom of conscience. In 2010, as part of the Affordable Care Act (“ACA”), Congress enacted a law requiring employers to cover some recommended preventive services without cost sharing. The law does not mention contraceptive coverage. But the Health Resources and Services Administration (“HRSA”), an agency within the Department of Health and Human Services (“HHS”), issued guidelines that required coverage of all FDA-approved contraceptives. At the same time, the government recognized that some employers hold sincere religious objections to providing insurance for coverage for contraception, especially certain contraceptives the employers considered to be abortifacients, but decided to exempt only a fraction of those employers—churches and their integrated auxiliaries—from the requirement. Other religious employers remained subject to the contraceptive mandate (“Mandate”) and were left either to violate their sincerely held religious beliefs or to be subjected to significant fines.

Years of litigation in dozens of cases followed. In *Burwell v. Hobby Lobby Stores, Inc.*, the Supreme Court held that the “contraceptive mandate imposes a substantial burden on the exercise of religion” that was unlawful under the Religious Freedom Restoration Act (“RFRA”). 134 S. Ct. 2751, 2779 (2014). Rather than extend the church exemption, however, HHS tried “accommodating” religious objectors who did not qualify for that exemption. That decision triggered a new round of litigation that generated decisions in nine federal courts of appeals. Ultimately, the Supreme Court vacated those decisions and instructed the courts of appeals to give the parties time to try to resolve their differences. *See Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016).

On October 6, 2017, in an effort to address serious religious and moral objections and finally bring the litigation to a close, the Departments of HHS, Labor, and the Treasury (“the Agencies”) issued interim final rules (“IFRs”) that keep the Mandate in place, but exempt religious and moral objectors from having to include contraceptive coverage in insurance plans offered to their employees. *See Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA*, 82 Fed. Reg. 47,792 (Oct. 13, 2017) (the “Religious Exemption Rule”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the*

1 ACA, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (the “Moral Exemption Rule”) (collectively, “the Rules”).

2 Plaintiffs—the States of California, Maryland, Delaware, New York, and Virginia—seek to
 3 reverse this considered decision, demanding that religious and secular groups facilitate services to
 4 which they deeply object. They allege that the new rules violate the Equal Protection Clause, the
 5 Establishment Clause, the Affordable Care Act, and the Administrative Procedure Act. They contend
 6 that the Rules interfere with “women’s access to essential health care” that is “guarant[eed]” by the
 7 ACA. Mem. in Supp. of Pl.’s Mot. for a Prelim. Inj. at 1, ECF No. 28 (“PI Br.”). Those positions,
 8 if adopted, would apply equally to sweep away the longstanding exemption for churches and their
 9 integrated auxiliaries, exposing churches to the Mandate for the first time.

10 The federal government acted lawfully in making a policy choice in accordance with laws
 11 protecting religious liberty. Both the ACA and RFRA provide firm statutory authority for the Rules.
 12 And it is settled law that the government may accommodate religion without running afoul of the
 13 Equal Protection Clause or the Establishment Clause. This case is not about “permitt[ing] nearly *any*
 14 employer to impose their religious and moral beliefs on their workers (and dependents).” PI Br. at 2.
 15 It is about protecting a narrow class of sincere religious and moral objectors from being forced to
 16 facilitate practices that conflict with their beliefs.

17 But this Court should not reach the merits at all, because the Plaintiffs lack standing. The
 18 Plaintiffs seek to enjoin Rules that do not apply to them and that do not affect any identified state
 19 residents, and it is black-letter law that a state cannot assert the rights of its citizens against the federal
 20 government. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 610 n.16 (1982). And
 21 even if they had standing, Plaintiffs are in the wrong court: Venue is not proper here.

22 The States also fail to meet the four-part test for preliminary injunctive relief. They have not
 23 shown that they face irreparable harm—or indeed that they face injury to their own legally cognizable
 24 interests at all. Nor are Plaintiffs likely to succeed on the merits of any of their various claims. The
 25 Rules did not require yet another round of notice and comment; they do not discriminate on the basis
 26 of sex, but draw distinctions based on the presence or absence of a sincere religious or moral
 27 objection; they do not advance religion, but relieve a burden on religious practice; and finally, the
 28

Rules are not arbitrary, as they alleviate a substantial burden on religion and help resolve years of litigation and dozens of cases. Finally, the balance of harms and the public interest also weigh against the Court issuing an injunction. The broad position that Plaintiffs advocate would undermine religious exercise and freedom of conscience, while on the other side of the ledger, the Rules certainly will not affect the “vast majority of women” or “impact over half of the U.S. population.” PI Br. at 1, 20. The Mandate remains in place for the vast majority of employers, and the Plaintiffs’ own contraceptive coverage requirements (except in Virginia) would require much of the coverage that the States say would be dropped. The motion should be denied.

BACKGROUND

In March 2010, Congress enacted the ACA. *See* Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111–148, 124 Stat. 119 (2010), *as amended by* Pub. L. No. 111–152, 124 Stat. 1029 (2010). Section 1001 of the PPACA added section 2713 to the Public Health Service Act (PHSA). *See* 42 U.S.C. § 300gg-13. That provision requires group health plans and health insurance issuers that offer group or individual health coverage to provide coverage for certain preventive services without cost-sharing. *Id.* These include, “with respect to women, such additional preventive care and screenings not described in [§ 300gg-13(a)(1)] as provided for in comprehensive guidelines supported by [HRSA].” *Id.* § 300gg-13(a)(4). Congress did not require HRSA to include contraceptive services, and the ACA does not mention such services.

Congress exempted tens of millions of employees from the preventive services provision, many because their employers sponsor “grandfathered plans,” which are those “in which an individual was enrolled on March 23, 2010” that also comply with certain additional regulations. *See* 26 C.F.R. § 54.9815–1251(a); 29 C.F.R. § 2590.715–1251(a); 45 C.F.R. § 147.140(a). Congress required grandfathered plans to cover certain services deemed “particularly significant,” including coverage of preexisting conditions and allowing dependents to remain on plans until age 26, but did not require coverage of preventive services. 75 Fed. Reg. 34,357, 34,540 (June 17, 2010).

On August 1, 2011, HRSA adopted guidelines that defined as covered preventive services the full range of FDA-approved contraceptive methods, sterilization procedures, and patient

1 education and counseling for women with reproductive capacity. *See* HRSA, Women’s Preventive
 2 Services: Required Health Plan Coverage Guidelines (“Guidelines”), [http://www.hrsa.gov/womens-](http://www.hrsa.gov/womens-guidelines)
 3 guidelines. Simultaneously, the Agencies issued a second set of IFRs (“Interim Final Rules”) providing an exemption for certain religious employers. *See* Group Health Plans and Health
 4 Insurance Issuers Relating to Coverage of Preventive Services Under the PPACA, 76 Fed. Reg. 46,621, 46,625 (Aug. 3, 2011). The IFRs limited the exemption to “churches, their integrated
 5 auxiliaries, and conventions or associations of churches,” as well as “the exclusively religious activities of any religious order,” which are exempt from taxation under 26 U.S.C. § 501(a). The
 6 Agencies requested comments on the amended interim final regulations and specifically on the definition of a “religious employer.” 76 Fed. Reg. at 46,623.

11 After considering thousands of comments,¹ the Agencies issued final regulations that adopted the interim rules’ definition of a religious employer. 77 Fed. Reg. 8,725, 8,726–27 (Feb. 15, 2012).
 12 Around the same time, the Agencies created a temporary enforcement safe harbor for plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage
 13 that would not qualify as exempt religious employers (and for any associated group health insurance coverage).²

17 The safe harbor did not extend to for-profit companies with religious objections to providing coverage for contraceptive services or to companies of any kind with moral objections to providing
 18 such coverage. Dozens of organizations and individuals filed lawsuits challenging the Mandate. Courts around the country began to issue injunctions against the Mandate. *See Archdiocese of St.*
 19 *Louis v. Burwell*, 28 F. Supp. 3d 944, 954 (E.D. Mo. 2014) (citing cases).

22 As part of their continuing attempt to resolve religious objections, the Agencies issued an advance notice of proposed rulemaking (“ANPRM”) in March 2012 and a Notice of Proposed
 23 Rulemaking (NPRM) in February 2013. 77 Fed. Reg. 16,501 (Mar. 21, 2012). The Agencies’ goal

25 ¹ These comments are available at: <https://www.regulations.gov/docket?D=HHS-OS-2011-0023>.

26 ² On February 10, 2012, HHS issued a guidance describing the safe harbor and stating that the Agencies would wait one year before enforcing the mandate against certain non-exempt religious
 27 organizations. This guidance was later reissued without changing the substance of the policy in order to extend the safe harbor an additional year. *See* HHS, Guidance on the Temporary Enforcement Safe Harbor, at 1 n.1 & 3 (Feb. 10, 2012), <https://go.usa.gov/xnZBN>.

1 was to address alternatives for providing women access to contraceptive services without cost-
 2 sharing and for accommodating religious organizations' liberty interests, *id.* at 16,501–03, and to
 3 give “an early opportunity for any interested stakeholder to provide advice and input into the policy
 4 development relating to the accommodation to be made” in amendments to the regulations, *id.* at
 5 16,503.

6 After receiving over 400,000 comments,³ the Agencies published final rules. 78 Fed. Reg.
 7 39,870 (July 2, 2013). These rules simplified the religious employer exemption by defining a
 8 “religious employer” to be “an organization that is organized and operates as a nonprofit entity and
 9 is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as
 10 amended.” *Id.* at 39,889. That Code provision refers *only* to churches, their integrated auxiliaries,
 11 conventions or associations of churches, and the exclusively religious activities of any religious
 12 order. *Id.*

13 But the 2013 final rules did not extend the religious employer exemption to all objecting
 14 organizations. Instead, they established an “accommodation” for group health plans established or
 15 maintained by “eligible organizations.” *Id.* at 39,874–80, 39,896. Under this process, an eligible
 16 organization was not required “to contract, arrange, pay, or refer for contraceptive coverage” to
 17 which it had religious objections, *id.* at 39,874, if it completed a self-certification stating that it was
 18 an eligible organization and provided a copy of that form to its issuer or third-party administrator
 19 (“TPA”). *Id.* at 39,878–79. The organization’s health insurance issuer or TPA would then be
 20 required to provide or arrange separate payments to participants and beneficiaries for contraceptive
 21 services without cost sharing, premium, fee, or other charge to participants or beneficiaries, or to the
 22 eligible organization or its plan.⁴ *See id.* at 39,875–80.

23 The 2013 final rules did not resolve the litigation challenging the Mandate. In 2014, the
 24 Supreme Court held that, at least as applied to closely-held for-profit corporations with religious
 25 objections to providing contraceptive coverage, the Mandate violated RFRA. *Hobby Lobby*, 134 S.

26 ³The comments on the ANPRM and NPRM are available at
 27 <https://www.regulations.gov/docket?D=CMS-2012-0031>.

28 ⁴ For self-insured plans, any costs incurred by a TPA could be reimbursed through an adjustment to
 Federally-facilitated Exchange (“FFE”) user fees. *See* 78 Fed. Reg. at 39,880.

1 Ct. at 2775. The Court explained that the “contraceptive mandate substantially burden[ed] the
2 exercise of religion” by those employers because it put them to the choice of violating their sincerely
3 held religious beliefs or facing significant fines. *Id.* at 2757. The Court also held that applying the
4 Mandate to the plaintiffs failed the least restrictive means test, because the accommodation was a
5 less restrictive alternative to applying the Mandate directly. *See id.* at 2779–80. The Court cautioned
6 that it was not deciding “whether an approach of this type complies with RFRA for purposes of all
7 religious claims.” *Id.* at 2782.

8 Less than a week later, the Court granted interim relief in a case involving Wheaton College,
9 a non-profit employer that sincerely believed that the accommodation process rendered it complicit
10 in providing contraceptive coverage. *See Wheaton Coll. v. Burwell*, 134 S. Ct. 2806, 2808 (2014).
11 The Court identified an alternative form of accommodation for Wheaton College whereby the
12 employer could notify the government—instead of its insurer or third-party administrator—of the
13 employer’s religious objections. *Id.* at 2807.

14 In light of that order, the Agencies issued a third set of IFRs to augment the regulatory
15 accommodation process. Coverage of Certain Preventive Services Under the ACA, 79 Fed. Reg.
16 51,092 (Aug. 27, 2014). They also issued a second NPRM to extend the accommodation process to
17 closely held for-profit entities with religious objections to contraceptive coverage in light of the
18 decision in *Hobby Lobby*. *See* 79 Fed. Reg. 51,118 (Aug. 27, 2014). After receiving over 75,000
19 comments, the Agencies finalized both the August 2014 IFRs and the August 2014 proposed rules.
20 *See* 80 Fed. Reg. 41,318, 41,324 (July 14, 2015).

21 Meanwhile, the litigation about whether the accommodation process satisfied the
22 government’s RFRA obligations toward non-profit religious entities generated a split among the
23 federal appeals courts, and the Supreme Court granted certiorari in *Zubik v. Burwell* to resolve it.
24 But on May 16, 2016, the Court issued a *per curiam* opinion vacating the judgments of the courts of
25 appeals and remanding the cases “[i]n light of the . . . substantial clarification and refinement in the
26 positions of the parties” in supplemental briefs they had submitted. 136 S. Ct. at 1560. The Court
27 stated that it anticipated that, on remand, the courts of appeals would “allow the parties sufficient
28

1 time to resolve any outstanding issues between them.” *Id.*

2 The Agencies then issued a Request for Information (“RFI”) seeking public comment on
3 options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and
4 the Court’s remand order. In response to the RFI, the Agencies received over 54,000 public
5 comments.⁵ *See* FAQs About ACA Implementation Part 36 (“FAQs”) (Jan. 9 2017).⁶ On January
6 9, 2017, the Agencies issued a “FAQ” noting that, after a review of the comments and considering
7 various options, the Agencies could not find a way to amend the accommodation so as to satisfy
8 objecting organizations while pursuing the Agencies’ policy goals. *See id.* Thus, the litigation on
9 remand, involving dozens of cases and dozens of plaintiffs, remained unresolved.

10 On May 4, 2017, the President issued an “Executive Order Promoting Free Speech and
11 Religious Liberty.” Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 4, 2017). It instructed the
12 Agencies to “consider issuing amended regulations, consistent with applicable law, to address
13 conscience-based objections to the preventive-care mandate promulgated under section
14 300gg-13(a)(4).” *Id.* Consistent with the Executive Order, the Agencies concluded that it was
15 “appropriate to reexamine the exemption and accommodation scheme currently in place for the
16 Mandate,” and issued the Rules at issue here on October 6, 2017. Religious Exemption Rule, 82
17 Fed. Reg. 47,799; Moral Exemption Rule, 82 Fed. Reg. 47,838. The Agencies have requested public
18 comments on the Rules by December 5, 2017.

19 The Religious Exemption Rule expands the exemption for non-governmental plan sponsors
20 that object to providing coverage for all or a subset of contraceptive services based on sincerely held
21 religious beliefs, as well as for institutions of higher education in their arrangement of student health
22 plans, to the extent of these entities’ sincerely held religious beliefs. 45 C.F.R. § 147.132(a)(2). The
23 Moral Exemption Rule provides an exemption for certain non-governmental plan sponsors that
24 object to providing all or a subset of contraceptive services based on sincerely held moral
25 convictions, as well as for institutions of higher education in their arrangement of student health
26

27 ⁵ These comments are available at <https://www.regulations.gov/docket?D=CMS-2016-0123>.

28 ⁶ Available at <https://go.usa.gov/xnWVG> and <https://go.usa.gov/xnWVs>.

plans, to the extent of these entities' sincerely held moral convictions. *Id.* § 147.133(a)(2).⁷

Under the Rules, HRSA remains free to define "contraceptive services" as "contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv)" for all non-exempt employers. *See* 82 Fed. Reg. at 47,835; 45 C.F.R. §§ 147.132(c), 147.133(c). "Contraceptive services" do not include contraceptive services for men, and never have, because the ACA only authorizes HRSA to develop guidelines for "additional preventive care and screenings" to be covered "with respect to women." 42 U.S.C. § 300gg-13(a)(4); 78 Fed. Reg. 8,456, 8,458 n.3 (Feb. 6, 2013) (excluding "services relating to a man's reproductive capacity, such as vasectomies and condoms" from the definition of "preventive services" that must be provided without cost sharing).⁸ As under the previous rule, exempt entities are not required to self-certify, but they are still subject to regulatory disclosure requirements for plan exclusions or reductions in a covered benefit. 82 Fed. Reg. at 47,808 & n.54; *id.* at 47,804 & n.32. The Rules also maintain the accommodation process as a voluntary mechanism to provide contraceptive availability for women covered by the plans of exempt entities that choose to use it. 45 C.F.R. § 147.131; 26 C.F.R. § 54.9815-2713A; 29 C.F.R. § 2590.715-2713A. On October 6, 2017, HRSA updated its Guidelines to exempt entities and individuals that qualify for exemptions from the Guidelines' requirements. Guidelines, <http://www.hrsa.gov/womens-guidelines>.

ARGUMENT

I. PLAINTIFFS LACK STANDING.

As an initial matter, this Court lacks jurisdiction to adjudicate Plaintiffs' claims because they lack standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). The standing inquiry is

⁷ Each rule also includes an "individual exemption" that allows a willing plan sponsor of a group health plan or a willing health insurance issuer offering group or individual health insurance coverage to provide a separate benefit package option or separate policy, certificate, or contract of insurance to an individual who objects to coverage for contraceptive services based on sincerely held religious beliefs or moral convictions. 45 C.F.R. §§ 147.132(b), 147.133(b).

⁸ Contrary to Plaintiffs' suggestion, PI Br. at 20, "[c]ontraceptive services" under the Rules also do not include drugs or methods approved by the FDA for contraceptive use that are prescribed for medical treatment, because 42 U.S.C. § 300gg-13(a)(4) does not apply to non-preventive care provided for treatment of an existing condition. *See* 82 Fed. Reg. at 47,805 & n.48. In other words, if drugs or methods approved by the FDA for contraceptive use are used for a non-contraceptive purpose, the Rules do not exempt them from coverage (if they would otherwise be covered by a plan).

1 “especially rigorous” where, as here, a plaintiff asks a federal court “to decide whether an action
2 taken by one of the other two branches of the Federal Government was unconstitutional.” *Raines v.*
3 *Byrd*, 521 U.S. 811, 819-20 (1997).⁹

4 The challenged Rules apply to non-governmental employers, not to states. They do not
5 command the States to take, or refrain from taking, any action. The States nonetheless seek to
6 challenge the Rules based on conjecture about the indirect or incidental financial consequences that
7 allegedly will flow from them. They fail to show that the Rules will result in any injury for the
8 States, much less that an injury is “*certainly* impending.” *Lujan*, 504 U.S. at 564 n.2.

9 Plaintiffs’ first theory of harm is that the expanded exemptions will “force[]” women to rely
10 on statewide programs, imposing a “financial and administrative burden of ensuring access to
11 contraceptive coverage” on the States’ finances. First Am. Compl. ¶¶ 47-52, 57-62, 66-71, 79-84, 88-
12 94, ECF No. 24; PI Br. at 29-32. But conclusory allegations that a state’s budget or tax revenues
13 will be harmed in some general way by a federal policy are not sufficient to support standing. *See*,
14 *e.g.*, *Pennsylvania v. Kleppe*, 533 F.2d 668, 672-73 (D.C. Cir. 1976); *Wyoming v. U.S. Dep’t of the*
15 *Interior*, 674 F.3d 1220, 1234 (10th Cir. 2012); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

16 Although the States repeatedly and falsely claim that “millions of women” and more than
17 “half of the U.S. population” will be affected (PI Br. at 10, 20), Plaintiffs have failed to show that
18 any particular employer will imminently avail itself of the exemption, rather than the
19 accommodation.¹⁰ They have also failed to allege that the employees of such an employer would
20 lack access to contraceptive coverage through, for example, a family member’s plan. And they
21 ignore the fact that many employers may be required to cover contraception under Plaintiffs’ own
22 “contraceptive equity” laws (except in Virginia), even if the objecting organizations invoked the

23
24 ⁹ As to Count IV, a state is not a “person” protected by the Due Process Clause of the Fifth
25 Amendment. *See South Carolina v. Katzenbach*, 383 U.S. 301, 323-34 (1966); *United States v.*
26 *Thoms*, 684 F.3d 893, 899 n.4 (9th Cir. 2012). As to Count III, Plaintiffs cite no case recognizing
27 the standing of a state to bring an Establishment Clause challenge, and it is not clear how a State can
suffer “spiritual or psychological harm” or have “religious beliefs” that can be “stigmatized.” *See Catholic League for Religious & Civil Rights v. City & Cty. of San Francisco*, 624 F.3d 1043, 1050-53 (9th Cir. 2010).

28 ¹⁰ Employers seeking the exemption are subject to ERISA’s timely disclosure requirements for plan
exclusions or reductions in a covered service or benefit. *See* 82 Fed. Reg. at 47,808 & n.54.

1 federal exemptions to the ACA’s Mandate. *Cf.* PI Br. at 31. In short, Plaintiffs have failed to
 2 sufficiently allege that any State residents will imminently lose coverage as a result of the expanded
 3 exemptions.

4 Even if state residents do lose coverage as a result of the Rules, the States’ alleged harms rely
 5 on an attenuated chain of causation. It is speculation that “women [denied] access [to] cost-free
 6 contraceptive coverage through their health plan” will seek coverage through (and qualify for) state-
 7 funded programs, thus requiring increased state spending, *see* PI Br. at 31; that expanded exemptions
 8 “will likely cause unintended pregnancies to rise”; or that the Rules will “burden” the States with
 9 “funding a significant portion of the medical procedures associated with unintended pregnancies and
 10 their aftermath.” PI Br. at 29-30. The costs of such “unintended pregnancies” would likely be
 11 covered by these employees’ health plans. Moreover, the expanded exemptions do not “forc[e]”
 12 anyone to forgo contraceptive use, much less “forc[e]” eligible individuals to seek subsidized
 13 contraception, prenatal care and delivery services from state programs. Any purported “costs of lost
 14 opportunities for affected women to achieve” and “to contribute as taxpayers” is similarly unavailing.
 15 *Id.* at 30. If such hypothetical impacts on state finances were enough to establish Article III standing,
 16 a state could challenge virtually any federal policy.¹¹ *See Wyoming*, 674 F.3d at 1234 (requiring
 17 “concrete evidence” of an impact on state finances given the “the unavoidable economic
 18 repercussions of virtually all federal policies”).

19 The States also allege that they will “face increased costs of providing contraception to their
 20 residents.” PI Br. at 31. But a state has suffered no legally cognizable injury if an eligible person
 21 applies for a benefit that a state has voluntarily elected to provide (such as those available through a
 22 state’s family planning program). *See Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976)
 23 (holding that “[n]o State can be heard to complain about damage inflicted by its own hand”).

24 Nor can the States overcome their lack of standing by asserting a right as *parens patriae* to

25 _____
 26 ¹¹ Even if the States had alleged fiscal injuries traceable to the Rules, those injuries would not suffice
 27 to confer the States with standing on their own behalf. The States’ generalized allegations of harm
 28 to their finances or loss of increased tax revenue are not proprietary interests apart from the interests
 of their citizens. *See City of Rohnert Park v. Harris*, 601 F.2d 1040, 1044-45 (9th Cir. 1979); *People*
ex rel. Hartigan v. Cheney, 726 F. Supp. 219, 225 (C.D. Ill. 1989).

1 represent the interests of their citizens. *See* First Am. Compl. ¶ 14. A state can sue a private party
 2 to protect its *parens patriae* interest in the health and well-being of its citizens. *Snapp*, 458 U.S. at
 3 602-03. But it cannot bring such a suit against the federal government. *See Massachusetts v. Mellon*,
 4 262 U.S. 447, 485-86 (1923). “It is the United States, and not the state, which represents [its citizens]
 5 as *parens patriae*,” and “it is no part of [a state’s] duty or power to enforce rights in respect of their
 6 relations with the federal government.” *Id.* at 485-86. This well-settled rule controls here.

7 Plaintiffs’ invocation of their “quasi-sovereign” interests similarly fails to establish standing.
 8 In *Massachusetts v. EPA*, 549 U.S. 497, 522-23 (2007), the Supreme Court allowed Massachusetts
 9 to sue the federal government to redress a concrete, direct injury to its quasi-sovereign interests;
 10 Massachusetts alleged harm to the physical integrity of its “sovereign territory,” damaging its
 11 “independent interest in all the earth and air within its domain.” *Id.* at 519. The States here allege
 12 no such concrete, direct injury to their own interests. Rather, they allege “quasi-sovereign” interests
 13 only in the health of their residents. First Am. Compl. ¶ 14. These are really the interests of the
 14 State’s citizens, which the States cannot assert as *parens patriae* against the federal government.
 15 *Snapp*, 458 U.S. at 602-03; *see also Massachusetts*, 549 U.S. at 520 n.17.¹²

16 ¹² In *Washington v. Trump*, 847 F.3d 1151, 1159 (9th Cir. 2017), *cert. denied*, 2017 WL 3224674
 17 (Nov. 13, 2017), and *Hawaii v. Trump*, 859 F.3d 741, 764 (9th Cir. 2017), *vacated as moot*, No. 16-
 18 1540 (U.S. Oct. 24, 2017), the Ninth Circuit held that the States could sue the federal government on
 19 behalf of their citizens under the third-party standing doctrine. The States do not, in this case, invoke
 20 third-party standing and, in any case, the plaintiff invoking third-party standing must have suffered
 an injury cognizable under Article III, *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004); *cf. Washington*,
 847 F.3d at 1159 (grounding State’s standing in proprietary interests as an operator of a university);
Hawaii, 859 F.3d at 765 (same), and as explained above, the Plaintiff States have not suffered such
 an injury here.

21 One state—Virginia—alleges that the expanded exemptions would affect its financial obligations
 22 through two state hospital systems, First Am. Compl. ¶ 93, but does not allege (i) that these hospital
 23 systems are state-funded, (ii) that any of the “at least 10 Virginia employers” “who will likely seek
 24 an exemption or accommodation” would seek an exemption and their employees would seek
 25 contraceptive services at these hospitals, *id.* ¶ 13, and (iii) that there is a hindrance to these third
 26 parties suing on their own behalf. *Cf. Washington*, 847 F.3d at 1159-60 (executive order injured
 27 specific students at universities that were branches of the states under state law); *Hawaii*, 859 F.3d
 28 at 764 (same for state-operated university). In any event, Virginia could not maintain this suit in this
 venue in the absence of California, which has not alleged such a proprietary injury.
 The vacated decision in *Hawaii* also found that the State had standing under an “alternative standing
 theory: that the Order impairs its sovereign interests” in carrying out state policies because the
 Executive Order at issue “would prevent the State from assisting with refugee resettlement,”
 impairing the State’s “sovereign interests in carrying out its refugee policies.” 859 F.3d at 765. This
 theory of state standing is incorrect, but in any event the States do not allege that the expanded
 exemptions prevent the States from enforcing their legal codes. Nor could they make such an

II. VENUE IS NOT PROPER IN THIS DISTRICT.

There are three possible bases for venue in official-capacity suits against a federal agency or officer: Suit may be brought in a district where “(A) a defendant in the action resides, (B) a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (C) the plaintiff resides if no real property is involved in the action.” 28 U.S.C. § 1391(e). With respect to the plaintiff’s residence, “[f]or all venue purposes,” a non-natural person “shall be deemed to reside . . . , if a plaintiff, only in the judicial district in which it maintains its principal place of business.” § 1391(c)(2); *see Brodt v. Cty. of Hartford*, 10 F. Supp. 3d 198, 201 (D.D.C. 2014) (applying § 1391(c)(2) to local governmental entity); *Springle v. City of New York*, 2013 WL 592656, at *8 (S.D.N.Y. Feb. 14, 2013) (same). Plaintiffs assert that venue is proper in this district because this is “a judicial district in which the State of California resides.” First Am. Compl. ¶ 6.

Venue is not proper here. Under § 1391, the State, as a plaintiff, resides only “in *the* judicial district in which it maintains its *principal* place of business.” § 1391(c)(2) (emphasis added). “Clearly, reference to ‘the’ and the singular ‘its principal place of business’ compels the conclusion that an entity plaintiff (unlike an entity defendant) can reside in only one district at a time.” 14D Federal Practice and Procedure § 3805 (4th ed.) (April 2017). The Supreme Court has defined principal place of business as the place where “officers direct, control, and coordinate the corporation’s activities. It is the place that the Court of Appeals have called the corporations ‘nerve center.’ And in practice it should normally be the place where the corporation maintains its headquarters.” *Hertz Corp. v. Friend*, 559 U.S. 77, 92-93 (2010) (defining “principal place of business” for diversity jurisdiction purposes); *see Carijano v. Occidental Petroleum Corp.*, 643 F.3d 1216, 1230 n.2 (9th Cir. 2011) (referencing *Hertz* definition in venue discussion).

Only one city can be the State’s “nerve center” and “headquarters”: Sacramento, the state capitol—“[t]he permanent seat of government of the state[.]” Cal. Gov’t Code § 450. Sacramento is both where the California legislature sits and the site of the Governor’s primary office and official

assertion; nothing in the Rules prevents a State from imposing its own contraceptive mandate or altering any such mandate already in place.

1 residence. It is also the official residence of the Governor's close advisors, Cal. Gov't Code § 11151,
 2 and the home to numerous government offices. In short, there is no plausible "principal place of
 3 business" for the State of California other than Sacramento. *See Bentley v. Ellam*, No. 89-5418, 1990
 4 WL 63734, at *1 (E.D. Pa. May 8, 1990). Sacramento is in the Eastern District of California,
 5 however, not this District. 28 U.S.C. § 84(b).

6 **III. PLAINTIFFS HAVE NOT SHOWN THAT PRELIMINARY RELIEF IS NEEDED** 7 **TO PREVENT IRREPARABLE HARM.**

8 Even if Plaintiffs had standing, the harms they allege—(1) an injury to their interest as *parens*
 9 *patriae* in the health and well-being of their residents, and (2) an injury in the form of increased
 10 costs, PI Br. at 28-32—are not irreparable harms supporting a preliminary injunction.

11 A merely economic injury typically does not provide a basis for preliminary injunctive relief.
 12 *Rent-A-Center, Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 603 (9th Cir.
 13 1991); *see also L.A. Mem'l Coliseum Comm'n v. Nat'l Football League*, 634 F.2d 1197, 1202 (9th
 14 Cir. 1980) (reversing preliminary injunction and holding that lost revenues did not constitute
 15 irreparable harm). Furthermore, as noted above, *see* § I, Plaintiffs' generalized allegation of financial
 16 harm is not distinct from the interests of their citizens, and they cannot premise the existence of
 17 irreparable harm on alleged injuries to their citizens.¹³ Nor do Plaintiffs show an irreparable injury
 18 by alleging constitutional claims. Because Plaintiffs are unlikely to succeed on the merits of those
 19 claims, they cannot rely on them as the basis for finding irreparable harm. *See Goldie's Bookstore,*
 20 *Inc. v. Superior Court of State of Cal.*, 739 F.2d 466, 472 (9th Cir. 1984) (alleged constitutional claim
 21 that was "too tenuous" in nature could not constitute per se irreparable harm).

22 Additionally, "a plaintiff must *demonstrate immediate threatened* injury as a prerequisite to
 23 preliminary injunctive relief." *Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 674 (9th Cir.

24 ¹³ Nor does Plaintiffs' asserted procedural injury, PI Br. at 29, constitute a threat of *irreparable*
 25 harm, as demonstrated in the very case cited by Plaintiffs. *See N. Mariana Islands v. United States*,
 26 686 F. Supp. 2d 7, 17 (D.D.C. 2009) (explaining that though a determination that an agency has
 27 violated the APA's notice-and-comment provisions might give rise to cognizable injury, "to justify
 28 the issuance of a preliminary injunction, the [plaintiff] must show that unless the rule is enjoined, [it]
 is likely to experience not just *some injury*, but *irreparable* harm that cannot be cured by ultimate
 success on the merits in this case") (emphasis added).

1 1988) (emphasis added); *see also Amylin Pharm., Inc. v. Eli Lilly & Co.*, 456 F. App'x 676, 679 (9th
 2 Cir. 2011). But Plaintiffs have alleged, at most, a threat of harm that might occur at some indefinite
 3 future time, not an imminent and immediate threatened injury. They allege that employers will seek
 4 an exemption for all contraception, rather than an accommodation, and that, as a result, the reduction
 5 in employer-based coverage of contraception will someday increase the number of unplanned
 6 pregnancies and/or significant health problems, which will lead to state-administered programs
 7 incurring costs at some future time, PI Br. at 29-30, and that some women will seek coverage for
 8 contraception costs through state-administered programs at some indefinite future date. *Id.* at 31-32.
 9 These allegations do not show that Plaintiffs face imminent irreparable harm absent emergency relief.

10 Furthermore, “[s]peculative injury does not constitute irreparable injury sufficient to warrant
 11 granting a preliminary injunction.” *Caribbean Marine Servs.*, 844 F.2d at 674 (citation omitted); *see*
 12 *also Park Vill. Apartment Tenants Ass’n v. Mortimer Howard Tr.*, 636 F.3d 1150, 1160 (9th Cir.
 13 2011). As shown by their own phrasing, Plaintiffs’ allegations that “contraceptive coverage *could*
 14 be dropped” by employers, PI Br. at 29 (emphasis added), are founded on multiple levels of
 15 speculation. Employers that eliminate coverage generally must provide their employees with 60
 16 days’ notice, or at least 30 days’ notice before the start of a plan year, *see* 82 Fed. Reg. at 47,813,
 17 and Plaintiffs have not identified any employers that have given such notice to any of their
 18 residents.¹⁴ Plaintiffs’ conjectures do not show an imminent irreparable harm.

19 **IV. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS.**

20 **A. Plaintiffs Are Unlikely to Succeed on Their Procedural APA Claim.**

21 Plaintiffs assert that the Rules should be enjoined because they were issued without notice
 22 and comment. First Am. Compl. ¶¶ 116-21; PI Br. at 15-19. That claim is meritless.

23 **1. The Agencies Issued the Rules Pursuant to Express Statutory Authority.**

24 The APA’s rulemaking provisions generally require that agencies provide notice of a
 25

26 ¹⁴ Instead, declarant Jonathan Werberg offers only the hearsay observation that “[t]here are a number
 27 of employers in New York State that have been identified to me as *likely* to use the exemption
 28 provided by the IFRs because of their involvement in previous litigation” Werberg Decl. ¶ 5,
 ECF No. 28-16. The “number of employers” is three, none of whom is alleged to have provided
 such notice to its employees. *See id.* ¶¶ 6-8.

1 proposed rule, invite and consider public comments, and adopt a final rule that includes a statement
 2 of basis and purpose. *See* 5 U.S.C. § 553(b), (c). But the Rules were issued pursuant to express
 3 statutory authorization to “promulgate *any* interim final rules *as the Secretary determines* are
 4 appropriate” to promulgate regulations relating to health coverage. *See* 26 U.S.C. § 9833; 29 U.S.C.
 5 § 1191c; 42 U.S.C. § 300gg-92 (emphasis added). These provisions relating to health coverage IFRs
 6 are unique; they do not appear in other grants of regulatory authority. The Agencies relied on this
 7 statutory authority to issue the 2010, 2011, and 2014 IFRs regarding the Mandate. 75 Fed. Reg. at
 8 41, 726, 41,729-30 (July 19, 2010); 76 Fed. Reg. at 46,624; 79 Fed. Reg. at 51,095; *cf. Real*
 9 *Alternatives, Inc. v. Burwell*, 150 F. Supp. 3d 419, 427 n.6 (M.D. Pa. 2015) (noting that APA notice-
 10 and-comment requirements did not apply to the 2011 IFR under this specific statutory authority to
 11 issue IFRs). Accordingly, the Agencies have met the APA’s only procedural requirements that are
 12 applicable here: they have requested comments for a period of sixty days on the IFRs, and they will
 13 not issue final regulations until they receive and carefully consider these comments. *See* 82 Fed.
 14 Reg. at 47,792; 82 Fed. Reg. at 47,838.

15 Plaintiffs’ contrary position writes this express grant of statutory authority out of the statute.
 16 Under the States’ view, the grant of authority is meaningless; it would merely give the Secretaries
 17 the same authority they already possessed. But when Congress sets forth its “clear intent that APA
 18 notice and comment procedures need not be followed,” an agency may dispense with those
 19 requirements and issue an IFR. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C.
 20 Cir. 1994); *Asiana Airlines v. FAA*, 134 F.3d 393, 397-98 (D.C. Cir. 1998). The relevant question is
 21 “whether Congress has established procedures so clearly different from those required by the APA
 22 that it must have intended to displace the norm.” *Asiana Airlines*, 134 F.3d at 397. That is the case
 23 here. Express authority to issue “any interim final rules *as the Secretar[ies] determine[]* are
 24 appropriate” is “clearly different from [procedures] required by the APA,” which impose a standard
 25 of good cause, not appropriateness as deemed by the Secretaries. *Coalition for Parity, Inc. v.*
 26 *Sebelius*, 709 F. Supp. 2d 10, 17-18 (D.D.C. 2010).

2. The Agencies Had Good Cause to Issue Interim Final Rules.

In any event, the Agencies’ decision to issue the Rules on an interim final basis would have been justified under the APA itself. The APA authorizes agencies to dispense with the notice-and-comment rulemaking procedures “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor[e] in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(3)(B). That Congress “has specifically authorized the Secretaries to promulgate interim final rules,” at a minimum, “provides support towards a finding of ‘good cause’ to proceed without notice and comment.” *Coalition for Parity*, 709 F. Supp. 2d at 20.

And even without that thumb on the scale, good cause existed to issue the Rules without notice and comment.

First, the Agencies found that any additional delay in issuing the Rules would be contrary to the public interest. 82 Fed. Reg. at 47,814-15; 82 Fed. Reg. at 47,855–56. Prompt effectiveness would provide entities and individuals facing burdens on their sincerely held religious beliefs and moral convictions with important and urgent relief. *Id.* at 47,814; *see also id.* at 47,855.¹⁵ The Rules also resolve the uncertainty, inconsistency, and costs resulting from the dozens of lawsuits over the Mandate for nearly five years. *See Serv. Emps. Int’l Union, Local 102 v. Cty. of San Diego*, 60 F.3d 1346, 1352 n.3 (9th Cir. 1994) (finding good cause where “the federal courts were issuing conflicting decisions” and the agency had reviewed public comments six years before). Indeed, because more than a year has elapsed since the *Zubik* remand, some courts had begun pressing for resolution. *See, e.g., Order, Notre Dame v. Price*, No. 13-3853 (7th Cir), ECF Dckt. No. 150 (Aug. 14, 2017). The Religious Exemption Rule “provide[d] a specific policy resolution that courts ha[d] been waiting to receive from the [Agencies] for more than a year” following *Zubik*. 82 Fed. Reg. at 47,814.

Second, the Agencies demonstrated a willingness to consider public comment, both prior to and following issuance of the Rules. *See Priests for Life v. U.S. Dep’t of Health & Human Servs.*,

¹⁵ The clarity provided in the Rules also serves the public interest by removing barriers to participation in the insurance market and reducing the cost of health insurance. 82 Fed. Reg. at 47,815. And the Rules also remove any deterrent to objectors considering organizing entities that would be subject to the Mandate, or from offering health insurance in the first place. *Id.* at 47,814.

772 F.3d 229, 276 (D.C. Cir. 2014), *vacated and remanded by* *Zubik v. Burwell*, 136 S. Ct. 1557 (2016);¹⁶ *Conservation Law Found. v. Evans*, 360 F.3d 21, 29-30 (1st Cir. 2004). As discussed above, *see* pp. 7-9, the Agencies received and considered “more than 100,000 public comments on multiple occasions” on the exemption and accommodation issues. 82 Fed. Reg. at 47,814. After reviewing these thousands of comments, the Agencies could not find a way to amend the accommodation to fully eliminate the substantial burden on religious practice. But there is no question that the Agencies have “proceed[ed] in a fully informed manner” here. PI Br. at 18-19.

The Agencies have also solicited comments for 60 days following issuance of the Rules. *See* 82 Fed. Reg. at 47,792 (requesting comments on or before December 5, 2017); 82 Fed. Reg. at 47,838 (same). Their solicitation of post-promulgation comments “suggests that the [Departments have] been open-minded,” with the result that “real ‘public reconsideration of the issued rule’ [is taking] place.” *Petry v. Block*, 737 F.2d 1193, 1203 (D.C. Cir. 1984) (citation omitted) (in light of post-promulgation comment period, remand to the agency for further proceedings was unnecessary); *see also Republic Steel Corp. v. Costle*, 621 F.2d 797, 804 (6th Cir. 1980) (upholding rule where agency provided only post-promulgation comment period); *Universal Health Servs. of McAllen, Inc. v. Sullivan*, 770 F. Supp. 704, 721 (D.D.C. 1991).

Finally, the Rules are effective only until final rules are issued. “The interim nature of a challenged rule is a significant factor in evaluating an agency’s good cause claim.” *Nat’l Women, Infants, & Children Grocers Ass’n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 107 (D.D.C. 2006) (quotation omitted); *see also Mid-Tex Elec. Co-op., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987). These Rules are merely temporary. By seeking comments, the Agencies have given interested parties two full months to review the Rules before the Agencies issue final rules.

¹⁶ Plaintiffs attempt to distinguish the Agencies’ use of IFRs in 2010, 2011, and 2014 and the D.C. Circuit’s decision in *Priests for Life* by arguing that “the prior IFRs were promulgated under significantly different circumstances than these IFRs.” PI Br. at 17. But the Agencies noted similar reasons for good cause to issue the 2011 and 2014 IFRs, underscoring the long-recognized need for prompt guidance and clarity on the scope of these exemptions and accommodations. 76 Fed. Reg. at 46,624; 79 Fed. Reg. at 51,095. In addition, the *Priests for Life* court noted that the Agencies “reasonably interpreted the Supreme Court’s order in *Wheaton College* as obligating [them] to take action to further alleviate any burden on the religious liberty of objecting religious organizations.” *Priests for Life*, 772 F.3d at 276. So too here following the *Zubik* remand. 82 Fed. Reg. at 47,814.

Even if a single justification “standing alone” would not constitute good cause, the court must consider whether the “combined effect” suffices. *Nat’l Women Ass’n*, 416 F. Supp. 2d at 107; *Mid-Tex Elec. Coop., Inc.*, 822 F.2d at 1132-33. The factors discussed above – whether considered individually or together – justified the Rules’ reliance on the “good cause” exception. *See Nat’l Women Ass’n*, 416 F. Supp. 2d at 104–05.

3. If the Lack of Formal Notice-and-Comment Was an Error, It Was Harmless.

In any event, any error in forgoing notice and comment was harmless. The APA’s judicial review provision instructs courts to take “due account ... of the rule of prejudicial error.” 5 U.S.C. § 706. Courts routinely apply this instruction when they determine whether an agency has failed to comply with the APA’s notice-and-comment requirement. *See Paulsen v. Daniels*, 413 F.3d 999, 1007 (9th Cir. 2005) (lack of notice-and-comment was harmless because “interested parties received some notice that sufficiently enabled them to participate in the rulemaking process”); *Idaho Farm Bureau Federation v. Babbitt*, 58 F.3d 1392 (9th Cir. 1995); *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479 (9th Cir. 1992); *Sagebrush Rebellion, Inc. v. Hodel*, 790 F.2d 760, 764-65 (9th Cir. 1986). The burden falls on the party asserting error to demonstrate prejudice. *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009).

Here, the Rules were issued after the Agencies received “more than 100,000 public comments” throughout six years of publishing and modifying these regulations, providing an extensive discussion about whether and by what extent to expand the exemptions at issue here. 82 Fed. Reg. at 47,814. The States cannot bear their burden of showing prejudice, *see Paulsen*, 413 F.3d at 1006, because they, like all interested parties, have had multiple opportunities to comment on the scope of the exemptions and accommodations following multiple rounds of rulemaking, including the issuance of three IFRs, one ANPRM, two NPRMs, and one RFI on these issues. *See* 75 Fed. Reg. at 41,726; 77 Fed. Reg. at 16,501; 81 Fed. Reg. 47,741 (July 22, 2016). Notably, the States do not allege any specific comments that they would have submitted on the Rules. And comments addressing each of the claims that the States now assert were submitted in response to earlier rounds of rulemaking. *See* Preliminary Partial Admin. Record (manual filing notification

1 attached as Exhibit 1). Finally, the States have another opportunity to comment on the expanded
 2 exemptions before final rules are issued.

3 **B. Plaintiffs Are Unlikely to Succeed on Their Substantive APA Claims.**

4 Plaintiffs contend that the Rules violate the APA’s substantive limits on legislative rules
 5 because they (1) are not in accord with various laws (including the ACA and RFRA) and (2) are
 6 arbitrary and capricious. PI Br. at 11-15, 19-21. These contentions are incorrect.

7 **1. The Rules are Valid under the APA because they are in Accordance with**
 8 **Law, and Not in Excess of Statutory Authority.**

9 Plaintiffs argue that “the new IFRs cannot be reconciled with the plain language of the ACA”
 10 which “makes plain that the ‘preventive care’ relating to ‘women’ ‘shall’ be provided.” PI Br. at 11.
 11 They also argue more generally that the Rules are in excess of statutory jurisdiction. *Id.* at 14-15.
 12 Both contentions are flawed.

13 Congress gave the Agencies wide discretion to craft minimum requirements for women’s
 14 preventive healthcare and screenings. The PHSA, as modified by the ACA, requires that covered
 15 group health plans “shall, . . . at a minimum provide coverage for . . . with respect to women, such
 16 additional preventive care and screenings . . . as provided for in comprehensive guidelines supported
 17 by [HRSA] for purposes of this paragraph.” 42 U.S.C. § 300gg-13(a) & (a)(4). Congress has also
 18 delegated general regulatory authority to the Agencies to “promulgate such regulations as may be
 19 necessary or appropriate to carry out the provisions” of the ACA. 42 U.S.C. § 300gg-92; 26 U.S.C.
 20 § 9833; 29 U.S.C. § 1191c. The Agencies acted within the clear authority granted to them under
 21 these statutes. *See Chevron U.S.A., Inc. v. Nat’l Res. Def. Council*, 467 U.S. 837, 842-43 (1984).

22 To begin, the text and structure of § 300gg-13 of title 42 reflect an undisputed grant of
 23 authority to the Agencies. Section (a) of that provision identifies four categories of services for
 24 which covered health plans must provide coverage without any cost-sharing requirements. 42 U.S.C.
 25 § 300gg-13(a)(1)–(4). The recommendations and guidelines noted in subsections (a)(1)–(3) were in
 26 existence at the time Congress enacted that statutory provision, but the guidelines described in
 27 subsection (a)(4) were not. For that reason, the Agencies have understood the reference to
 28

1 “comprehensive guidelines” in subsection (a)(4) as a grant of authority to develop them. The
2 Agencies, as administering agencies of the applicable statutes, and HHS, as the agency within which
3 HRSA is located, have general rulemaking authority to guide that development. *See* 42 U.S.C. §
4 300gg-92; 28 U.S.C. § 9833; 29 U.S.C. § 1191c; 47 Fed. Reg. 38,409 (Aug. 31, 1982). And since
5 their very first rulemaking on this subject in 2011, the Agencies have consistently interpreted that
6 broad authority to include the power to provide limited exceptions that reconcile the ACA’s
7 preventive-services provision with strongly held religious and moral views on the sensitive issue of
8 contraceptive coverage. *See, e.g.*, 76 Fed. Reg. at 46,625 (Aug. 3, 2011); 78 Fed. Reg. 39,889 (July
9 2, 2013).

10 The text of subsection (a)(4) confirms that the Agencies’ discretion extends to authority
11 exercised in the Rules. The language “such additional” preventive services as “supported ... for
12 purposes of this paragraph [(a)(4)]” makes clear that, unlike the preceding subsections, HRSA would
13 have discretion to develop guidelines that did not already exist and to define the entities that would
14 be subject to them. 76 Fed. Reg. at 46,623; *see also* 82 Fed. Reg. at 47,794. Significantly, subsection
15 (a)(4) differs from subsection (a)(3), which covers preventive services for children: While
16 subsection (a)(3) requires provision of those children’s services “provided for” by HRSA, subsection
17 (a)(4) requires provision of preventive services “as provided for” by HRSA. The use of the word
18 “as” reinforces Congress’s delegation to HRSA to determine not only the services covered, but the
19 manner or reach of that coverage. The breadth of the Agencies’ discretion is further underlined by
20 the omission from the statutory text of the requirement that the Guidelines cover all “evidence-
21 informed” services. *Compare* 42 U.S.C. § 300gg-13(a)(4), *with id.* at (a)(1) & (a)(3).

22 Even if the statutes were ambiguous, this Court must defer to the Agencies’ resolution of that
23 ambiguity. Nothing in the statutes prohibits the Agencies from creating exemptions. *See Chevron*,
24 467 U.S. at 843. The Agencies read the statutes to authorize them to craft or modify exemptions for
25 any contraceptive coverage mandate, and that reasonable construction must prevail.

26 Plaintiffs’ argument that the ACA contains an absolute requirement to cover preventive
27 services lacks merit. They ignore the text of the preventive services provision, which is limited to
28

1 services “as provided for in comprehensive guidelines supported by the Health Resources and
 2 Services Administration.” § 300gg-13(a)(4). Indeed, Plaintiffs’ quotation of the statute omits that
 3 key provision, replacing it with ellipses. PI Br. at 11. More generally, Plaintiffs interpret the ACA
 4 to mean that the Guidelines can *never* allow exemptions. That position would forbid even the
 5 longstanding, narrower exemption for churches that has existed since the ACA’s early days,
 6 potentially placing the entire contraceptive mandate in jeopardy under RFRA. And, as noted above,
 7 the statute expressly contemplates a policy decision about the types of preventive services for women
 8 to be covered under that subsection. Although the statute does not expressly mention exemptions,
 9 neither does the statute mention contraception. *See* 42 U.S.C. § 300gg-13(a)(4). Moreover,
 10 Congress itself indicated that it did not intend absolutely uniform coverage of preventive services
 11 when it excluded preventive services from the list of “particularly significant protections”
 12 grandfathered plans must offer. 75 Fed. Reg. 34,538, 34,540 (June 17, 2010). Thus, “of the 150
 13 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5
 14 million are estimated to be enrolled in grandfathered plans” not subject to the Mandate. 82 Fed. Reg.
 15 at 47,794. No federal law requires this exemption ever to be phased out. *Id.*

16 Nor, contrary to Plaintiffs’ argument, have the Agencies ignored the provision’s purpose. *See*
 17 PI Br. at 12. Plaintiffs take one broad statutory purpose—to increase access to preventive care—and
 18 elevate it above all others. “But no legislation pursues its purposes at all costs. Deciding what
 19 competing values will or will not be sacrificed to the achievement of a particular objective is the very
 20 essence of legislative choice” *Rodriguez v. United States*, 480 U.S. 522, 525 (1987).
 21 Notwithstanding Plaintiffs’ claim to the contrary, the Agencies did, in fact, consider the interests
 22 advanced by the Women’s Health Amendment. Indeed, HRSA kept the Mandate in place for nearly
 23 all applicable entities. The Agencies simply did not construe the Amendment to require them to
 24 pursue marginal advances to those interests at the expense of all other goals.

25 **2. The Agencies’ Rationales for Exercising this Discretion Were Not Arbitrary.**

26 The arbitrary and capricious standard is highly deferential, and presumes the validity of
 27 agency action. *Motor Vehicles Mfrs. Ass’n of U.S., Inc. v. Ruckelshaus*, 719 F.2d 1159 (D.C. Cir.

1 1983). A court may not substitute its judgment for that of the agency, *Citizens to Pres. Overton Park,*
 2 *Inc. v. Volpe*, 401 U.S. 402, 416 (1971), but must instead affirm an agency’s decision if a rational
 3 basis for that decision has been provided, even if the court disagrees. *E.g., Bowman Transp., Inc. v.*
 4 *Ark. Best Freight Sys.*, 419 U.S. 281, 285 (1974). Agency action is not arbitrary or capricious if it
 5 “is rational, based on consideration of the relevant factors and within the scope of the authority
 6 delegated to the agency by the statute.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins.*
 7 *Co.*, 463 U.S. 29, 42 (1983); *see also Overton Park*, 401 U.S. at 416.

8 Contrary to Plaintiffs’ assertions, *see* PI Br. at 19, agency action is not subject to any more
 9 searching standard of review simply because it represents a change in policy. *FCC v. Fox Television*
 10 *Studios, Inc.*, 556 U.S. 502, 515 (2009). The Agencies “need not demonstrate, to a court’s
 11 satisfaction, that the reasons for the new policy are better than the reasons for the old one.” *Id.* at
 12 515. Instead, it suffices that the new policy is permissible under the statute, that there are good
 13 reasons for it, and that the agency believes the new policy to be better. *Id.*

14 The Rules detail at length the numerous considerations that led the Agencies to conclude that
 15 extending a broader exemption and optional accommodation process to those with sincere religious
 16 or moral objections “better balance[s] the Government’s interest in ensuring coverage for
 17 contraceptive and sterilization services in relation to the Government’s interests, including as
 18 reflected throughout Federal law, to provide conscience protections . . . and to minimize burdens in
 19 . . . regulation of the health insurance market.” 82 Fed. Reg. at 47,793. Together, these rationales
 20 amply supply the “rational connection” that Plaintiffs claim the Agencies lack. PI Br. at 19.

21 First, the Agencies properly considered their interest in concluding the litigation over the
 22 previous rules. An agency does not act arbitrarily or capriciously where it considers the burdens of
 23 ongoing litigation when changing agency policy. *Associated Builders & Contractors of Texas, Inc.*
 24 *v. NLRB*, 826 F.3d 215, 229 (5th Cir. 2016). The litigation engendered by the Mandate has consumed
 25 substantial government resources and has required attention at the highest levels. Indeed, the *Zubik*
 26 litigation alone comprises 52 suits brought by over 1,000 plaintiffs. By extending the exemption,
 27 the Agencies have effectively provided the relief sought in those suits.

1 Second, an Executive Order provides an agency with a valid, non-arbitrary reason to act,
 2 because such Orders carry the weight of the President's Article II directive power. *See Myers v.*
 3 *United States*, 272 U.S. 52 (1926) (recognizing an implied directive power flowing from Article II's
 4 Appointments Clause, Executive Vesting Clause, and Take Care Clause). For purposes of the APA,
 5 an agency has a reasoned basis to enter into a rulemaking where the President has instructed it to do
 6 so. *See Sherley v. Sebelius*, 689 F.3d 776, 784 (D.C. Cir. 2012). The President's Executive Order
 7 (*see* p. 9 above) provides the Agencies with yet another valid reason for promulgating the Rules.

8 Third, the Agencies reconsidered the interests served by the former regulations and concluded
 9 that the interests served by applying the Mandate to certain organizations with sincere religious or
 10 moral objections to providing such contraception coverage did not justify the burden on conscience
 11 from requiring them to do so. The Agencies noted that Congress had not required any provision of
 12 contraceptive coverage under the ACA, that it had elected not to apply the preventive services
 13 provisions to grandfathered plans, and that the Agencies have provided exemptions from the Mandate
 14 since its creation.¹⁷ 82 Fed. Reg. at 47,800-802. The Agencies also determined that the
 15 administrative record was insufficient to overcome their concerns about these conscience objections,
 16 particularly in light of the lack of: evidence that contraceptive coverage accounts for a significant
 17 portion of the preventive services cost gap between men and women, the existence of numerous other
 18 governmental programs to assist low-income women to access free or subsidized contraception, the
 19 lack of tailoring between the Mandate and women most likely to experience unintended pregnancies,
 20 and the lack of evidence that access to contraceptive coverage significantly decreases unintended
 21 pregnancies with respect to those employed by an objector. 82 Fed. Reg. at 47,804.

22 Plaintiffs suggest that the new rule "reverse[s]" a prior agency decision, but this is overblown.
 23 *See* PI Br. at 13. Under the new Rules, HRSA has maintained the Mandate for contraceptive
 24 coverage without cost sharing for non-exempt plans, *see* Guidelines and 82 Fed. Reg. at 47,807, and
 25 the Agencies have kept the former accommodation process as an optional avenue for eligible
 26

27 ¹⁷ Congress's repeated efforts to protect religious beliefs and moral convictions in the healthcare
 28 context likewise weigh against applying the Mandate to organizations with sincere moral or religious
 objections. *See* 82 Fed. Reg. 47,792 n.1.

employers, *id.* at 47,806. The new Rules expand the kinds of employers who may take advantage of the exemptions, but the exemptions are nonetheless cabined to those with sincere religious and moral beliefs. *Id.*; 82 Fed. Reg. at 47,853-54 (scope of the individual moral exemption). The new exemptions also level the playing field for employers that share the same kinds of religious convictions that the old exemption rules were intended to address, but who would not previously have been eligible for an exemption for reasons unrelated to their religious objections—for example, the exemptions place religious orders on the same footing as churches. *See* 82 Fed. Reg. at 47,801. The Agencies anticipate that the new exemptions will only modestly expand the number of exempt employers vis-à-vis those who relied on the previous exemption or who obtained relief through litigation. *See id.* at 47,819; PI Br. at 19-20. Far from arbitrary or capricious agency action, the Rules demonstrate that the Agencies took care not to forsake the interests of the previous regulatory regime, while nonetheless moving to protect religious and moral beliefs.

Lastly, the Agencies indicated that the requirements of the ACA and RFRA, as well as Congress's historical attention to religious freedom, guided their decision to issue the Rules. *See* 82 Fed. Reg. at 47,793. Because agencies must consider all explicit and implicit statutory factors, *see Overton Park*, 401 U.S. at 412, and because they may only act within their statutory jurisdiction, *see* 5 U.S.C. § 706(2)(C), these considerations were not only proper, but compulsory. As discussed in § IV.B.4, below, these statutory provisions unambiguously dictate that the Agencies create the exemptions at issue here; but even if this Court determines that these statutory factors are ambiguous, the agencies are entitled to *Chevron* deference in reading the statutes to require them.

3. The Rules Otherwise Comply with the ACA.

The Rules do not violate the ACA's nondiscrimination requirement, 42 U.S.C. § 18116, or its prohibition on unreasonable barriers to healthcare, § 18114. With respect to § 18116, Plaintiffs are incorrect in their assertion that the Rules discriminate based on sex, PI Br. at 14, as discussed below at § IV.D. Nor do Plaintiffs cite any legal or other authority suggesting that narrowing requirements for contraceptive coverage constitutes sex discrimination.¹⁸ In addition, RFRA

¹⁸ Plaintiffs cite to one case that is inapposite; that court merely found that the plaintiffs were sufficiently injured to escape a motion to dismiss, and did not discuss § 18116 at all. *See Ferrer v.*

1 requires the Religious Exemption Rule, *see* § IV.B.4, and RFRA takes precedence over any
 2 obligations imposed by § 18116. 42 U.S.C. § 2000bb-3; *see also* 45 C.F.R. § 92.2(b)(2) (2016).

3 With respect to § 18114, Plaintiffs argue—also without legal authority—that the Rules create
 4 an unreasonable barrier to medical care. PI Br. at 14. However, the Rules merely narrow the
 5 coverage mandate rather than impose affirmative barriers on access to contraception. *Cf. Harris v.*
 6 *McRae*, 448 U.S. 297, 316 (1980) (“[A]lthough government may not place obstacles in the path of a
 7 woman’s exercise of her freedom of choice, it need not remove those not of its own creation[, such
 8 as indigency].”). Worse, under Plaintiffs’ interpretation, § 18114 would mandate the provision of
 9 all “appropriate medical care,”¹⁹ rendering the ACA’s extensive discussion of Essential Health
 10 Benefits surplusage. *See generally* 42 U.S.C. §§ 18021, 18022. In addition, Plaintiffs do not even
 11 argue that the purported barrier is *unreasonable*—a difficult showing given the numerous other
 12 programs providing contraception, *see* 82 Fed. Reg. at 47,803, and the continued availability of the
 13 accommodation. Finally, the need to add the Women’s Health Amendment to the ACA *after* both
 14 § 18116 and § 18114 were included demonstrates that neither provision was understood to provide
 15 an alternative mandate for preventive or contraceptive coverage. *Compare* 155 Cong. Rec. S11607,
 16 S11646 (daily ed. Nov. 19, 2009) (including the non-discrimination provision at § 1557 and the
 17 barriers provision at § 1554) *with* 155 Cong. Rec. S12265, S12277 (daily ed. Dec. 3, 2009) (adding
 18 the Women’s Health Amendment).

19 **4. RFRA Requires the Religious Exemption Rule.**

20 Plaintiffs also argue that RFRA does not support either Rule. PI Br. at 12-13. But the Moral
 21 Rule does not rely on RFRA, so the argument is a straw man. And Plaintiffs are simply incorrect
 22 with respect to the Religious Exemption Rule—it is required by RFRA.

23 As a general matter, “[u]nder RFRA, the Federal Government may not, as a statutory matter,
 24 substantially burden a person’s exercise of religion, even if the burden results from a rule of general

25 _____
 26 *CareFirst, Inc.*, -- F.Supp.3d --, 2017 WL 3025839 (D.D.C. July 17, 2017).

27 ¹⁹ Furthermore, § 18114 does not even define “appropriate medical care.” “Congress . . . does not
 28 alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does
 not, one might say, hide elephants in mouseholes.” *Whitman v. Am. Trucking Associations, Inc.*, 531
 U.S. 457, 468 (2001).

applicability.” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2006). But a law that imposes a substantial burden on the exercise of religion is allowed under RFRA if the government “demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. § 2000bb–1(b).

The Religious Exemption Rule reasonably concludes that the Mandate, even as modified by the accommodation, imposes a substantial burden on the exercise of religion. 82 Fed. Reg. at 47,800. Plaintiffs do not challenge this conclusion.

The Religious Exemption Rule also reasonably concludes that there is no compelling interest that justifies the imposition of this substantial burden on the exercise of religion. The relevant inquiry is not the governmental interests served by the Mandate in general, but rather the governmental interests served by applying the Mandate to the small percentage of employers with sincere religious or moral objections to it. *Hobby Lobby*, 134 S. Ct. at 2779.²⁰ The Rule’s preamble thoroughly discusses the Agencies’ rationale for determining that there is no compelling interest in imposing the Mandate on this small percentage of employers. 82 Fed. Reg. at 47,800–06. The Agencies explained, among other things, that: (i) the fact that Congress has never required private employers to offer contraceptive coverage undermines any argument that the government has a compelling interest in requiring a small subset of employers to provide such coverage over their sincere religious or moral objections, *id.* at 47,800–01; (ii) the underinclusiveness of the ACA undermines the claim of a compelling interest in the provision of cost-free contraceptives under the Mandate to that small subset of employers, 75 Fed. Reg. at 34,540 (noting that Mandate does not extend to grandfathered plans); (iii) the scope of the pre-existing religious and church-plan exemptions undercuts the

²⁰ Plaintiffs misread *Hobby Lobby* as holding that the government had a compelling interest in providing cost-free contraceptive coverage to the employees of objecting employers. PI Br. at 20. The Court did not so hold. The plurality opinion assumed that point for the sake of argument. *Hobby Lobby Stores*, 134 S. Ct. at 2780. Plaintiffs rely on Justice Kennedy’s concurrence, but his opinion, like the Court’s, was “premise[d]” on the “assumption” that the government had shown a compelling interest. *Id.* at 2785–86. In any event, the Government is unaware of any case in which a court has held that the Government has a compelling interest when the Government itself has not asserted such an interest.

1 argument that there is a compelling interest in requiring objecting entities to facilitate the provision
 2 of cost-free contraceptive coverage, *cf. Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652,
 3 1658-59 (2017); (iv) the Agencies have determined, in their expert judgment, that the administrative
 4 record does not contain adequate evidence to meet the high standard of proving a compelling interest
 5 in providing cost-free contraceptive services by objecting employers.

6 Nor, contrary to Plaintiffs' characterizations, PI Br. at 20, did the Agencies ignore
 7 considerations of women's health. The Rules leave the Mandate in place for most applicable entities.
 8 After canvassing the medical evidence, however, the Agencies concluded that, with regard to the
 9 evidence on the effect of contraceptives and broad coverage mandates on women's health, the record
 10 was more ambiguous than previously acknowledged and not adequate to establish a compelling
 11 interest. 82 Fed. Reg. 47,805. This technical judgment falls within the Agencies' expertise and so
 12 is entitled to deference. *Tri-Valley Cares v. U.S. Dep't of Energy*, 671 F.3d 1113, 1124 (9th Cir.
 13 2012). Moreover, Plaintiffs' effort to rely on declarations to demonstrate otherwise (PI Br. at 20)
 14 should be rejected, because this is an APA claim which should be reviewed on the administrative
 15 record. *See Earth Island Inst. v. Evans*, 256 F. Supp. 2d 1064, 1078 (N.D. Cal. 2003) (rejecting
 16 extra-record evidence at preliminary injunction stage, when the record had not yet been compiled).²¹

17 Plaintiffs also argue that "'person,' as defined in RFRA, does not extend to for-profit
 18 publicly-traded corporations." PI Br. at 13. But *Hobby Lobby*, relying in part on the Dictionary
 19 Act, 1 U.S.C. § 1, interpreted the term "person" in RFRA to include closely held for-profit
 20 corporations, *Hobby Lobby*, 134 S. Ct. at 2768-69, and added that "[n]o known understanding of the
 21 term 'person' includes *some* but not all corporations." *Id.* at 2769.

22 ²¹ Plaintiffs also argue that "there is no law that authorizes the Moral Exemption IFR." PI Br. at 13.
 23 To the contrary, as explained above, the ACA authorizes the Agencies, in conjunction with HRSA,
 24 to define the scope of the preventive services provided. Plaintiffs also observe that Congress did not
 25 enact proposed amendments that would have explicitly codified conscience protections. *Id.* at 13
 26 n.15. But "failed legislative proposals are a particularly dangerous ground on which to rest an
 27 interpretation of a prior statute." *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*,
 28 511 U.S. 164, 187 (1994) (citation omitted). Congress may decline to adopt a proposal for any
 number of reasons, including "that the existing legislation already incorporated the offered change."
Id. *See also* 158 Cong. Rec. S485 (2012) (statement of Sen. Reid) ("They are talking about first
 amendment rights, the Constitution. I appreciate that. But that is so senseless. This debate that is
 going on dealing with this issue, dealing with contraception, is a rule that has not been made final
 yet. There is no final rule. Let's wait until there is at least a rule we can talk about.").

Finally, Plaintiffs assert that “[t]o the extent that an employer has a religious objection, in compliance with RFRA, Defendants must still ensure that their female employees are not coerced to participate in the religious beliefs of their employer, such that women are deprived of their equal access to medical care.” PI Br. at 13. This coercion argument merely repackages the States’ assertion that the Religious Exemption Rule violates the Establishment Clause by unduly burdening third parties (women). This argument would eliminate the exemption for churches and other houses of worship, which Plaintiffs do not challenge. The States’ coercion theory also misreads *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985). PI Br. at 13, 23. That case involved a statute that “compel[led] people to act in the name of . . . religion” by requiring private employers to permit employees to take off work on their chosen Sabbath day, *Estate of Thornton*, 472 U.S. at 708. By contrast, the Religious Exemption Rule does not compel action by private employers, but leaves room for private employers to exercise their religion. This lifting of a government-imposed burden on religious exercise is permitted and even encouraged by the First Amendment. *See Tex. Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (plurality opinion). Nor does the Rule does require employees to “participate in the religious beliefs of their employer.” PI Br. at 13. Nothing in the Rule obligates women working for objecting employers to change their beliefs about contraceptives.

5. At a Minimum, the Religious Exemption Rule Was a Permissible Response to the Substantial Burden on Religious Exercise Imposed by the Mandate.

Even if RFRA did not *require* the expansion of the religious exemption, at a minimum, RFRA *authorizes* the Agencies to adopt the Religious Exemption Rule. The Supreme Court’s decision in *Hobby Lobby* makes clear that, absent some form of exemption or accommodation, the Mandate imposes a substantial burden on employers with religious objections to providing contraceptive coverage. 134 S. Ct. at 2775. Previously, the Agencies “attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA’s requirements for imposing that burden.” 82 Fed. Reg. at 47,806. But the Agencies’ attempts did not resolve the sincere religious objections asserted by dozens of employers, and instead led to half a decade of RFRA litigation and serial regulatory amendments. *Id.* at 47,814. Those efforts imposed

1 significant costs on the Agencies and the courts—as well as on regulated entities and their plan
 2 participants and beneficiaries, who were left uncertain about their legal rights and obligations. The
 3 Agencies thus reasonably determined that rather than engaging in further efforts to “revis[e] the
 4 accommodations previously offered”—an approach that would have entailed continued litigation in
 5 dozens of cases, with no foreseeable end—a broader exemption was “the most appropriate
 6 administrative response” to the substantial burden identified in *Hobby Lobby*. *Id.* at 47,806. The
 7 Agencies emphasized that they would have adopted the Religious Exemption Rule “[e]ven if RFRA
 8 does not compel [it].” *Id.*

9 The States essentially argue that the Agencies cannot go beyond what RFRA strictly requires.
 10 But that approach would place agencies in an impossible position when facing claims that statutory
 11 or regulatory requirements substantially burden the exercise of religion. On Plaintiffs’ view, an
 12 agency faced with such a claim would apparently be legally prohibited from affording an exemption
 13 unless it concluded that that no possible accommodation short of an exemption would be possible
 14 and consistent with RFRA. That is a recipe for protracted and unnecessary litigation. It is also
 15 inconsistent with the Supreme Court’s recognition in analogous contexts that an entity faced with
 16 potentially conflicting legal obligations should be afforded some leeway. For example, the Court
 17 has held that, under Title VII, an employer may “engage in intentional discrimination for the asserted
 18 purpose of avoiding or remedying an unintentional disparate impact” if the employer has “a strong
 19 basis in evidence to believe it will be subject to disparate-impact liability if it fails to take the race-
 20 conscious, discriminatory action.” *Ricci v. DeStefano*, 557 U.S. 557, 585 (2009). Critically, the
 21 Court did not require the employer to prove that it *actually would* “be subject to disparate-impact
 22 liability.” Instead, the Court adopted a more flexible standard that “appropriately constrains
 23 employers’ discretion in making race-based decisions” but was not “so restrictive that it allows
 24 employers to act only when there is a provable, actual violation”—a standard that would have left
 25 employers in an untenable position. *Id.* at 583. So too here.

26 **C. Plaintiffs Are Unlikely to Succeed on Their Establishment Clause Claim.**

27 Plaintiffs allege that the Rules violate the Establishment Clause. PI Br. at 21-24. To the
 28

contrary, the Rules represent a constitutional exercise of executive authority to alleviate unjustified substantial burdens on the exercise of non-religious moral convictions and religious beliefs.

When government relieves such burdens, it does not violate the Establishment Clause. “[I]n commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice.” *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 705 (1994). Rather, “government may (and sometimes must) accommodate religious practices.” *Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334 (1987). And “‘there is room for play in the joints between’ the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.” *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005). Thus, the Supreme Court has upheld a broad range of accommodations, including the exemption of religious organizations from Title VII’s prohibition against discrimination in employment on the basis of religion, *Amos*, 483 U.S. at 335-39; a state property tax exemption for religious organizations, *Walz v. Tax Comm’n of N.Y.*, 397 U.S. 664, 672-80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *Zorach v. Clauson*, 343 U.S. 306, 315 (1952).

The Supreme Court and the Ninth Circuit continue to apply the three-part test articulated in *Lemon v. Kurtzman*, 403 U.S. 602 (1971), to evaluate Establishment Clause challenges to government acts seeking to accommodate the practice of religious beliefs. *See Amos*, 483 U.S. at 335; *Johnson v. Poway Unified Sch. Dist.*, 658 F.3d 954, 972 (9th Cir. 2011). “Under *Lemon*, a government act is consistent with the Establishment Clause if it: (1) has a secular purpose; (2) has a principal or primary effect that neither advances nor disapproves of religion; and (3) does not foster excessive governmental entanglement with religion.” *Johnson*, 658 F.3d at 972 (citations omitted). The Rules easily satisfy that test.

With respect to *Lemon*’s first prong—that the government act serves a secular legislative purpose—it is a permissible legislative purpose to alleviate significant governmental interference with the exercise of religion. *Amos*, 483 U.S. at 335; *see also Bowen v. Kendrick*, 487 U.S. 589, 602

(1988). This was the precise aim of the executive branch in promulgating the Religious Exemption Rule. *See* 82 Fed. Reg. at 47,793. And the aim of the executive branch in promulgating the Moral Exemption Rule was secular: to accommodate moral convictions not based in religion. 82 Fed. Reg. at 47,844. Although Plaintiffs complain that the government met with religious organizations before issuing the Rules, the government also met with a number of secular health care groups who opposed expanding the exemptions.²²

The first prong of the *Lemon* test “does not mean that the law’s purpose must be unrelated to religion—that would amount to a requirement that the government show a callous indifference to religious groups, and the Establishment Clause has never been so interpreted.” *Mayweathers v. Newland*, 314 F.3d 1062, 1068 (9th Cir. 2002). Rather, “a practice will stumble on the purpose prong only if it is motivated *wholly* by an impermissible purpose,” such as “to endorse or disapprove of religion.” *Am. Family Ass’n v. City & Cty. of San Francisco*, 277 F.3d 1114, 1121 (9th Cir. 2002). Moreover, the court’s “analysis under this prong focuses purely on *purpose*; we do not question the propriety of the means to achieve that purpose or whether the defendants were correct or even reasonable in the assumptions underlying their actions” *Id.*

Here, nothing in the Rules shows any intent to advance any particular faith or to promote religion in general. Instead, the Rules merely seek to alleviate certain substantial hardships faced by entities and individuals in the provision of health care. Indeed, the fact that the Rules apply to entities and individuals with secular, non-religious moral beliefs regarding the provision of contraception confirms that the Rules possess a secular purpose.

The second prong of the *Lemon* test requires that a law’s “principal or primary effect . . . neither advance[] nor inhibit[] religion.” *Lemon*, 403 U.S. at 612. Removing barriers to the exercise of religious freedom does not advance religion; to the contrary, “there is ample room for accommodation of religion under the Establishment Clause.” *Amos*, 483 U.S. at 338. The Rules do not promote or subsidize a religious belief or message; instead, they merely free entities and

²² *See* Office of Information and Regulatory Affairs, EO 12866 Meetings Search Results, <https://www.reginfo.gov/public/do/eom12866SearchResults?pubId=&rin=0938-ZB38&viewRule=true>.

1 individuals with objections to providing coverage for contraception based on religious beliefs and
 2 moral convictions to practice those beliefs and convictions as they otherwise would in the absence
 3 of certain government-imposed regulations. The Rules “merely accommodate[] and protect[] the
 4 free exercise of religion, which the Constitution allows.” *Mayweathers*, 314 F.3d at 1069.

5 The Rules satisfy the third prong of *Lemon* because they do not “entangle the State in an
 6 unlawful fostering of religion.”²³ *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136,
 7 145 (1987). In *Amos*, the Supreme Court upheld a statutory provision that exempted religious groups
 8 from Title VII’s prohibition against religious discrimination, stating that “[i]t cannot be seriously
 9 contended that [the statute] impermissibly entangles church and state; the statute effectuates a more
 10 complete separation of the two . . .” *Amos*, 483 U.S. at 339. The Rules operate in a similar manner:
 11 they reduce state interference with religious exercise. By relieving religious institutions from certain
 12 government-imposed burdens, the Rules in fact achieve a more complete separation of church and
 13 state. *See Mayweathers*, 314 F.3d at 1069.²⁴

14 **D. Plaintiffs Are Unlikely to Succeed on Their Equal Protection Claim.**

15 Plaintiffs argue that the Rules violate the equal protection component of the Fifth
 16 Amendment’s Due Process Clause. PI Br. at 25-28; see *United States v. Windsor*, 133 S. Ct. 2675,
 17 2695 (2013) (citations omitted). That argument is meritless.

18 When faced with a claim of discrimination on the basis of sex, courts assess (i) whether the
 19 classification is facially based upon sex and, if not, (ii) whether there are other factors—such as the
 20 purpose of the law or the existence of a disparate impact—that demonstrate an invidious intent to
 21 discriminate on the basis of sex. *See Personnel Adm’r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979).

22 ²³ In *Agostini v. Felton*, 521 U.S. 203 (1997), the Supreme Court stated that “the factors used to
 23 determine the ‘effect’ of a challenged action were similar to those used to determine whether there
 24 was an excessive entanglement.” *Barnes-Wallace v. City of San Diego*, 704 F.3d 1067, 1083 (9th
 25 Cir. 2012) (citing *Agostini*, 521 U.S. at 232-33). As shown herein, the Rules pass the entanglement
 26 inquiry, regardless of whether it is understood to be a separate factor or merely part of the inquiry
 27 into the Rules’ effect. Additionally, the “coercion test” mentioned in cases such as *Lee v. Weisman*,
 505 U.S. 577 (1992), is not relevant here. That test applies not to Establishment Clause challenges
 generally, but specifically where the government sponsors religious exercises. The Rules do not
 coerce anyone into supporting or participating in religion or its exercise.

28 ²⁴ Plaintiffs rely on *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985), in support of their
 argument, but, as explained above, that reliance is misplaced. *See* § IV.B.4 above.

1 With regard to “this second inquiry, impact provides an important starting point, but purposeful
 2 discrimination is the condition that offends the Constitution.” *Id.* (citations omitted). Sex-based
 3 distinctions are subject to intermediate scrutiny, meaning that the distinction must be substantially
 4 related to an important governmental interest. *Wengler v. Druggists Mut. Ins. Co.*, 446 U.S. 142,
 5 150 (1980). All other distinctions that do not target a protected class or burden a fundamental right
 6 are subject to rational-basis review. *Heller v. Doe*, 509 U.S. 312, 319–20 (1993). Under this
 7 standard, “a classification must be upheld ... if there is any reasonably conceivable state of facts that
 8 could provide a rational basis for the classification.” *Id.* at 320 (citation omitted).

9 Plaintiffs contend that the Rules discriminate against women on their face because they
 10 “single out only women’s health benefits.” PI Br. at 25. In the alternative, Plaintiffs assert that even
 11 if the Rules are not facially discriminatory, they otherwise discriminate on the basis of sex because
 12 (i) they rely on overbroad generalizations about women’s healthcare (as demonstrated by use of the
 13 word “sensitive”), (ii) they impact women, not men, and (iii) the Agencies’ position that there is no
 14 compelling interest in contraceptive coverage evinces a discriminatory intent. *Id.* at 27-28.

15 The Rules do not discriminate against women on the basis of sex, facially or otherwise. The
 16 Rules and HRSA Guidelines generally require coverage for female contraceptives, while providing
 17 an exemption for those with religious and conscience objections. The Rules and Guidelines do not
 18 require any coverage of male contraceptives. *See* 78 Fed. Reg. at 8,458 n.3. Nor could they: The
 19 statutory provision requiring coverage for additional preventive services supported by HRSA
 20 pertains only to such services for “women.” 42 U.S.C. § 300gg-13(a)(4). Thus, the Rules do *not*
 21 treat men more favorably, and any sex-based distinctions flow from the statute requiring preventive
 22 services for women only, not from the Agencies improperly “singl[ing] out” women. Moreover,
 23 any distinctions in coverage among women are not premised on sex, but on the existence of a
 24 religious or moral objection to facilitating the provision of contraceptives.

25 No other factor reflects any invidious intent to discriminate on the basis of sex. The assertion
 26 that the Rules rely on overly broad generalizations regarding women likewise fails. Plaintiffs never
 27 develop the argument beyond pointing to the Rules’ use of the word “sensitive.” PI Br. at 27. But
 28

the word, which is used twice in the Religious Exemption Rule and several more times in the Moral Exemption Rule, is not used to describe women (as Plaintiffs seem to suggest), but to convey the fact that the Rules involve issues “calling for tact, care, or caution in treatment,” Merriam Webster Dictionary, <https://www.merriam-webster.com/dictionary/sensitive> (last visited Nov. 28, 2017) (defining “sensitive”). *See, e.g.*, 82 Fed. Reg. at 47,838. Nor does the Agencies’ conclusion regarding the lack of a compelling interest in these circumstances demonstrate an intention to discriminate against women: The Rules explain the non-discriminatory reasons for the conclusion (addressing medical evidence in the course of doing so), *see, e.g.*, 82 Fed. Reg. at 47800-06, and this conclusion is not inconsistent with Supreme Court precedent, *Hobby Lobby*, 134 S. Ct. at 2780, 86 (assuming, *but not deciding*, that there is a compelling interest in providing contraceptive coverage).

Because the Rules do not create sex-based distinctions, they are subject to rational basis review. They satisfy this “lowest level of scrutiny,” *United States v. Dumas*, 64 F.3d 1427, 1429 (9th Cir. 1995), because they are rationally related to legitimate government interests, *Lyng v. Int’l Union*, 485 U.S. 360, 370 (1988). The Religious Exemption Rule accommodates religion by “provid[ing] conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts.” 82 Fed. Reg. at 47,793. And the accommodation of religious beliefs is an important government interest, as the Supreme Court recognized in *Cutter*, 544 U.S. at 724-25. For the same reasons, the Rule would satisfy intermediate scrutiny.

The Moral Exemption Rule also has a rational basis (and satisfies intermediate scrutiny). It is designed to protect “sincerely held moral convictions” by exempting those with such convictions from facilitating the provision of contraceptive services. 82 Fed. Reg. at 47,839. The government may permissibly accommodate deeply held moral, but not religious, convictions and has furthered this important interest in a variety of contexts since the founding. *See Welsh v. United States*, 398 U.S. 333 (1970); *United States v. Seeger*, 380 U.S. 163 (1965); *Doe v. Bolton*, 410 U.S. 179 (1973); 82 Fed. Reg. at 47,838 n.1. Indeed, some of the Plaintiffs protect moral beliefs in healthcare. *See, e.g.*, Cal. Health & Safety Code § 123420; Md. Code Ann., Health – Gen. § 20-214.

V. THE BALANCE OF EQUITIES AND PUBLIC INTEREST MAKE INJUNCTIVE RELIEF INAPPROPRIATE

The balance of hardships and the public interest militate against issuing the injunction here. Where the government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Plaintiffs have not carried the burden of persuasion because they have not adequately alleged harm that would outweigh the public interest. Some religious organizations have long been able to claim an exemption to the contraceptive coverage regulations—this rule simply equalizes the availability of those exemptions for others with similar beliefs. *See* 82 Fed. Reg. at 47,794. Moreover, except in Virginia, only employees covered under self-insured plans could ever be affected by the Rules, because each of the other Plaintiff States has a “contraceptive equity” law. *See* PI Br. at 31. On the other side of the ledger, if the Court were to issue an injunction, the critical public interest in protecting religious liberty and conscience would be undermined. For that reason, the government, the public at large, and the individual employers with burdened²⁵ beliefs have a strong interest in seeing the Agencies exercise their statutory mandate with the discretion Congress intended. *See Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008).

CONCLUSION

The Court should deny Plaintiffs’ motion for a preliminary injunction.

²⁵ If the Court rules in Plaintiffs’ favor, the Court should return the parties to the position that they were in before the rules were issued, which is that the Agencies were actively considering policy responses to the *Zubik* remand. In no event should the Court issue a mandatory injunction directing Defendants to *enforce* the previous contraceptive coverage requirement. Such an injunction could conflict with the Supreme Court’s *Zubik* remand order prohibiting the government from imposing fines and penalties on objecting employers, and would require a significantly higher showing than the Plaintiffs could make. *Punnett v. Carter*, 621 F.2d 578, 582 (3d Cir. 1980). That type of injunction could also inappropriately generate dueling injunctions between this Court and the other district courts that have enjoined the government from enforcing the requirement against certain religious employers. *See, e.g., Newland v. Burwell*, 2015 WL 1757148 (D. Colo. Mar. 16, 2015); *Dordt Coll. v. Sebelius*, 22 F. Supp. 3d 934 (N.D. Iowa 2014). Finally, because Plaintiffs’ arguments regarding irreparable harm turn on state-specific circumstances, any injunction should not extend nationwide, and should be limited to the parties before this Court. *See Lewis v. Casey*, 518 U.S. 343, 357 (1996).

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